

## Food and Drug Administration, HHS

## § 338.50

338.3 Definition.

### Subpart B—Active Ingredients

338.10 Nighttime sleep-aid active ingredients.

### Subpart C—Labeling

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AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

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### Subpart A—General Provisions

#### § 338.1 Scope.

(a) An over-the-counter nighttime sleep-aid drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

#### § 338.3 Definition.

As used in this part:

*Nighttime sleep-aid.* A drug that is useful for the relief of occasional sleeplessness by individuals who have difficulty falling asleep.

### Subpart B—Active Ingredients

#### § 338.10 Nighttime sleep-aid active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in § 338.50(d):

- (a) Diphenhydramine hydrochloride.
- (b) Diphenhydramine citrate.

### Subpart C—Labeling

#### § 338.50 Labeling of nighttime sleep-aid drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a “nighttime sleep-aid.”

(b) *Indications.* The labeling of the product states, under the heading “In-

dications,” one or more of the phrases listed in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) (“Helps you” or “Reduces time to”) “fall asleep if you have difficulty falling asleep.”

(2) “For relief of occasional sleeplessness.”

(3) “Helps to reduce difficulty falling asleep.”

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “Do not give to children under 12 years of age.”

(2) “If sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness.”

(3) “Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.”

(4) “Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.”

(5) “Do not use [bullet]<sup>1</sup> with any other product containing diphenhydramine, even one used on skin”.

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”:

(1) *For products containing diphenhydramine hydrochloride identified in § 338.10(a).* Adults and children 12 years of age and over: Oral dosage is 50 milligrams at bedtime if needed, or as directed by a doctor.

<sup>1</sup>See § 201.66(b)(4) of this chapter for definition of bullet symbol.